Specification

Be It Known That We, **DAVID F. ZHOU, NAISHU WANG, CLAUDIA J.R. SHEN**, and **ANGELA J.Q. SHEN** all citizens of the United States of America and residents of San Diego, County of San Diego, State of California have invented a new and useful

SPECIMEN COLLECTION AND STORAGE AND TRANSPORT DEVICE AND METHOD

of which the following is a specification:

Prior Application

This is a continuation-in-part of patent application Serial Number 10/407,496 filed April 3, 2003 which is a continuation-in-part of Serial Number 10/205,712 filed July 25, 2002.

Field of the Invention

This invention relates to methods and devices practiced and used in the collection, preservation, transportation and analysis of fluid, viscous or particulate solid or otherwise flowable or sequacious material samples of chemical, biological or environmental material including tissues, bodies, food, and soil, and more specifically to instruments used for specimens of fecal matter for screening the gastrointestinal tract for bleeding and colorectal cancer, or other similar biological materials.

Background of the Invention

Several devices and methods have been used in the past to collect, preserve, transport and dispense chemical, environmental or biomedical specimens including fecal samples for later analysis by a laboratory or for clinical studies. The most common Guaiac Dye Test has been a dried smear paper pad, upon which, in the case of fecal samples, three consecutive specimens are smeared with dietary restrictions, covered then sent for analysis. One of the most common problems associated with this hundred years old device and method is dehydration. Even under rehydrating conditions, a fecal occult blood test of dry samples on paper pads will give a high rate of false positive or negative results. A false positive result may trigger a relatively expensive colonoscopic or barium enema examination that will probably or eventually eliminate the false

diagnosis. In the case of a false negative result, an early stage colorectal cancer may be missed, and if then metastasis occurs, the cancer may become incurable.

Another fecal sample collection device of the prior art comprises a simple cylindrical tube with a cap having a breakable tip and a plastic stick connected to the inside of the screw cap. The tube contains a certain amount of extraction buffer. The stick is inserted into fresh feces several times then put back into the tube and the cap is tightly secured to seal the tube. The main advantage of this procedure is that the extraction buffer keeps the fresh specimen wet and a preserving reagent mixed therewith may slow down the degradation of the biological molecule or its markers. While this method constitutes a substantial improvement over the smear paper devices of the past, unintended breakdown of the tip on top of the cap has occurred during manipulation or mailing of the specimen resulting in leakage and possible contamination. Moreover, specimens have a tendency to include excessive amounts of fecal material for the fixed amount of preservative or reagent contained in the tube resulting in false positive analysis. Another improved device of the prior art is disclosed in U.S. Patent No. 6,063,038 Diamond et al. In this case, a filtering membrane is provided between the body of the shipping vessel which holds the specimen and a preserving/reagent solution and the hollowed inside of the stick itself which can be accessed through a self-sealing membrane to extract a part of the liquid containing only the amount of specimen that passed through the filtering membrane. This improved device still suffers from a high risk of spillage of the preservative/reagent and a lack of quantitative mixing of the sample and preserving/reagent fluid.

Other devices provide for the dry storage of fecal material as disclosed in Kozak et al. U.S. Patent No. 6,299,842 for purposes such as occult blood assays that detect labile exoantegens,

but are not suited to carrying non-dry samples.

Due to the high cost of skilled labor used to manually manipulate and perform tests on the samples, devices which encourage greater automation and automation efficiency are generally preferred.

Because of the private and personal nature of fecal specimen collecting, collection is often performed by the relatively untrained donor. Further, because of the distasteful nature of feces, donors often have difficulty properly collecting or otherwise handling the fecal material. There is a need, therefore, for a device which reduces the handling of feces and the potential for close contact.

The instant invention results from some attempt to provide a practical solution to the problems and disadvantages of the aforesaid devices of the prior art.

Summary of the Invention

The principal and secondary objects of this invention are to provide a convenient, safe and inexpensive to manufacture device and method for collection by a patient or unskilled person of fresh fecal or other biological, chemical or environmental specimens in a quantitatively metered manner and for the preservation and leakproof shipping of the specimen through the mail to a laboratory for further storage and analysis while avoiding degradation of the specimen through unwanted dehydration or the imbalanced combination of specimen and preserving agents, and optionally providing for preservation of an amount of dry material.

These and other valuable objects are achieved by providing a simple tubular vessel closed at one end by a breakable hollow nib or other releasable sealing device, that is engaged at the

opposite end by a cap or stopper from which a stick axially projects into the vessel. At the distal end of the tip, a sample-holding portion has at least one radial or axial cavity and preferably indentations in the form of a spiral or helicoidal groove. As the stopper and stick are progressively inserted into the vessel by a screwing movement, the sample-holding portion passes through an aperture defining a narrow channel in the center of a septum in the median section of the vessel. The cross-section of the non-grooved part of the sample-holding portion and/or the shank portion adjacent to the sample-holding portion closely match the cross-sectional profile of the aperture so that any excess specimen matter which is not contained within the profile, is conveniently wiped out and prevented from passing into the most distal chamber of the vessel that contains a preserving fluid. Optionally, the excess specimen is usefully stored in the proximal chamber in the presence of a desiccant or drying material. The shank of the stick right behind the sample-holding portion seals the specimen-holding chamber so that the amount of specimen and preserving fluid are quantitatively balanced and remain so until part or all of the fluid is extracted for analysis after breaking of the sealing nib. A cover, shaped and dimensioned to safely cap the breakable nib can be tightly screwed upon the closed end of the vessel to protect the nib during manipulation and shipping of the device. The wet specimen-holding chamber is thus doubly sealed at opposite ends to ensure against leakage both before and after specimen collection. A padded or spring suspension shipping container made from inexpensive disposable plastic provides a third seal and enhanced protection. A disposable, telescopingly extendible handle is conveniently provided within the shipping container. The handle is shaped at one end to temporarily secure to the stopper opposite the stick allowing the collector to stab at feces in a toilet without contacting the toilet water by hand. The outer surface of the vessel can be shaped

to have a gentle taper which allows more close packing of an array of adjacent vessels in a test carrier. The plug can be further adapted to allow it to be releasably mountable to the vessel using common automated machinery.

Brief Description of the Drawing

Figure 1 is a cross-sectional side view of a biological specimen-collecting device according to the invention;

Figure 2 is a partial cross-sectional side view of the septum portion of an alternate embodiment of a specimen-collecting device according to the invention;

Figure 3 is a diagrammatic cross-sectional side view of the device of Figure 1 carried within a shock-resistant transport capsule;

Figure 4 is a diagrammatic cross-sectional side view of the device of Figure 1 carried within an alternate embodiment of the shock-resistant transport capsule;

Figure 5 is a diagrammatic cross-sectional side view of a plurality of devices according to Figure 4 loaded into an automated testing carriage;

Figure 6 is a diagrammatic perspective view of an extended handle for mounting the stopper for toilet sampling;

Figure 7 is a cross-sectional side view of the transport container of Figure 4 carrying the collapsed handle of Figure 6;

Figure 8 is a diagrammatic cross-sectional side view of an alternate embodiment of a specimen collecting device according to the invention; and

Figure 9 is a diagrammatic perspective view of the end section plug of the device of

Figure 8.

Description of the Preferred Embodiment of the Invention

Referring now to the drawing, there is shown a first embodiment of a device **1** specially adapted to collect a specimen of fecal or other chemical or biological matter, store and preserve it while it is mailed to a laboratory for analysis. The device comprises a tubular, preferably cylindrical, vessel **2** having a first end **3** closed and defining an access port **4** which is releasably sealed by a hollow nib **5** that can be easily broken to open the access port and allow convenient dispensing. The opposite, normally open, end **6** of the vessel is engaged by a stopper **7** comprising a knob **8** and a threaded plunger **9**. Screw threads **10** matingly cooperating with the threaded plunger are provided along the inside wall of the vessel from the second end **6** down to a median portion **11** of the vessel. A stick **12** projects axially from the stopper, more specifically, from the conical distal end **13** of the plunger into the vessel. The stick comprises a shank **14** and a sample-holding distal portion **15**. The sample-holding portion consists an oblong cylindrical member into which indentations **16** in the form of an helicoidal groove have been cut. The radius of the distal portion is substantially the same as the radius of the cylindrical shank **14**.

A conical transversal septum **17** in the median portion **11** of the vessel divides the vessel into a first chamber **18** sealed by the closed end **3** and a second chamber **19** accessible through the second end **6**. An aperture or passageway **20** in the middle of the septum is axially lined up with the stick **12** and has a cross-sectional geometry substantially symmetrical with that of the stick, that is a radius substantially equal to the radius of the shank **14** and sample-holding portion **15**. The cooperatively conically shaped distal end **13** of the plunger and septum **17** allow for

enahnced resiliency, thereby providing a positive seal over a larger range of plunger positions.

When the knob **8** of the stopper is turned clockwise, the sample-holding portion **15** of the stick progressively translates from the second chamber **19** into the first chamber **18** through the passageway constituted by the aperture **20** until such time as a distal part of the shank **14** engages and seals the aperture.

A cover **21** shaped and dimensioned to cap the closed first end **3** and end-breakable nib **5** has a threaded inner wall section **22** that cooperates with a correspondingly threaded area **23** on the outer wall of the vessel to secure the cover and thus, protect the breakable nib **5**.

The end section **24** that mounts the breakable nib **5** at the first end **3** of the vessel is not molded integrally with the wall of the vessel, but constitutes a separate plug which is installed only after the first chamber **18** has been filled with the preserving fluid **25**. The end section **24** is preferably bonded to the vessel to seal against fluid leaks. Such bonding can be permanent through use of an adhesive for example, or semi-permanent by dimensioning the plug to create a pressure seal for example. Alternately, the bond can be machine removable as described in a later embodiment. It should be noted that this bonding of the end section and the cover **21** that further occludes both the access port **4** controlled by the breakable nib and the one sealed by the end section plug **24**, combined with the double seal provided by the shank **14** of the stick closing the aperture **20** and the stopper **7** closing the second end **6** of the vessel assures against any leakage of the preserving fluid during shipment, before and after collection of the specimen.

The device may be used as follows. At the factory, with plunger **9** fully or partially screwed into the second end of the vessel and the aperture **20** sealed, a measured volume of preserving liquid **25** is introduced into the first chamber through the first end **3** which is then

sealed by the installation and bonding of the end section **24**. The volume is measured to provide the desired concentration of specimen that will eventually be found in suspension in the liquid. The device is marked about the first end **3**, such as on the cover **21**, with a legend such as "For Laboratory Use" or "Lab End". The knob **8** or upper area of the vessel is marked with another legend such as "Open Here" or "Patient End". The device is then packaged and distributed for use.

The collection of the specimen by the patient or an assisting individual goes as follows. Holding the stopper **7** by the knob and after unscrewing it and separating it from the vessel, the user plunges the sample-holding portion **15** of the stick into a volume of matter to be analyzed. The stick is then inserted back into the vessel and the stopper is screwed down until the sample-holding portion passes completely through the aperture **20** of the septum. During this procedure, the walls of the aperture coming into intimate contact with the non-threaded part of the sample-holding portion and shank, wipe out any excess material which is not held within the helicoidal groove, preventing that excess material from reaching the first chamber. Accordingly, only a quantitively metered amount of specimen matter is allowed into the first chamber. The first chamber contains the metered volume of preserving fluid **25**, preferably a liquid which will remain in contact with the specimen matter throughout storage and transportation of the vessel until part or all of it is drained for analysis by breaking the nib **5**.

It should be noted that the preserving liquid in the first chamber could be safely secured initially by a breakable barrier across the aperture **20** of the septum or by a resiliently self-sealing aperture. In which case, at the factory, the stopper would be only partially engaged into the vessel, keeping the sample-holding portion into the second chamber. Only after collection of the

specimen would the stopper be completely screwed into the vessel and the sample-holding portion forced through the septum. Instead of the end section **24**, the first end of the vessel could be closed by a diaphragm through which a self-sealing access port can be practiced by means of a syringe or any other equivalent releasable sealing structure.

Referring now to Figure 2, there is shown the median portion of an alternate embodiment of the device for collecting, storing, preserving, transporting and analyzing chemical or biological samples such as fecal specimens wherein a vessel **30** having an end **31** engaged by a stopper **32** having an axially projecting stick **33** which comprises a shank **34** and an oblong cylindrical sample-holding distal portion **35** having indentations **36** in the form of a helicoidal groove. The radius of the distal portion is substantially smaller than the radius of the cylindrical shank thereby allowing a greater amount of sample material **37** to be carried thereon.

A cylindrical transversal septum **40** in the median portion **41** of the vessel divides the vessel into a first chamber **42** and a second chamber **43**. An aperture or passageway **44** in the middle of the septum is sized to closely bear against the shank **34** of the stick **33** so that the aperture is effectively sealed by the stick.

Translation of the stick **33** from the second chamber **43** into the first chamber **42** through the passageway causes accumulation of an amount of excess sample **45** on the surface of the septum **40** facing the second chamber **43**. A hollow cylindrical disk of dessicant **46** such as silica gel or clay is located inside the second chamber proximate to the septum **40**.

Referring now to Figure 3, there is shown an alternate embodiment of a device **51** for collecting, storing and protectively transporting fecal or other similar chemical, biological or environmental material. The device formed similarly to the previous embodiment has a generally

cylindrical vessel **52** having a gently tapering diameter. The entire vessel is loadable into a sealable shipping capsule **53** which comprises a pair of open-ended cups **54, 55** matable at the open ends **56, 57** along an annular snap connector **58**. Each cup has a closed end **59, 60** having cushion pad **61, 62** formed onto the inner surface. The capsule is preferably made from an inexpensive, durable, fluid-resistant material such as polyethylene plastic.

Referring now to Figure 4, there is shown an alternate embodiment of a device **65** for collecting, storing and protectively transporting fecal or other similar chemical biological matter. The device formed similarly to the previous embodiment has a generally cylindrical vessel **66** having a gently tapering diameter. The entire vessel is loadable into a sealable shipping capsule **67** which comprises an oblong cup **68** having an open end **69** and an end cap **70** for closing the capsule. The end cup is preferably formed to have an axially located spring pedestal **71** having a frustoconical outer surface **72** sized to engage and bear against a cylindrical pocket **73** axially formed into an end of the knob **74** of the stopper of the vessel **66**. The end cap is formed from a material which allows a slight flexibility in the pedestal thereby providing a shock-resistant, springing support for the vessel. The capsule is preferably made from an inexpensive, durable, fluid-resistant material such as polyethylene plastic.

Referring now to Figure 5, there is shown a number of generally cylindrical vessels **80, 81, 82** having a gently tapering diameter as in the device of Figure 4. The overall taper has been greatly exaggerated in this figure to show that each vessel can be readily inserted into one of an array of adjacent holes **83, 84, 85** in a testing carriage **86**. The taper allows each vessel to be inserted narrow diameter end first into a hole where in sinks through the hole until the increasing diameter reaches the inside diameter of the hole. The structure of the vessel can therefore be said

to have an axially medial surface portion **92** having a narrower diameter or axial cross-section than an adjacent axially medial surface portion **93**. In this way, the vessel is securely held in place within the carriage. Adjacent vessels are similarly held. The tapering allows a close bunching together of adjacent vessels, even allowing contact between adjacent vessels at the broad diameter end **87, 88**, thereby allowing the carriage to carry an increased number of vessels. This structure also provides a wider top opening **89** allowing for greater error in the location of each of the flexible testing probes **90** which access the fluid within the vessel in an automated testing fashion. The angle **A** formed between the vertical and the tapered surface of the vessel is selected to provide close packing while accommodating existing carriers and providing adequate vessel volume. In most common applications for a linear taper, the angle **A** is preferably between about 0.25 and 5.0 degrees. Although the present embodiment discloses a linear taper providing a generally frusto-conical shape to the vessel, those skilled in the art will readily appreciate non-linear tapers. Referring now to Figure 6, there is shown telescopingly extendible handle **75** having a tapered tip portion **76** sized and shaped to frictionally and releasably engage a cylindrical pocket **77** axially formed into the end of the knob portion of a stopper. The handle further comprises a medial telescoping member **78** coaxially formed about the end prong member and coaxially and slidingly mounted within a proximal handle portion member. The handle allows the user to conveniently collect a fecal sample from a toilet without contacting the toilet water.

Referring now to Figure 7, there is shown the handle **75** in a collapsed configuration having overall dimensions which allow it to be stored within the capsule **67** of Figure 4. In this way, the vessel capsule and handle can be efficiently packaged and provided to the user.

Referring now to Figures 8 and 9, there is shown an alternate embodiment of the device

for collecting, storing and protectively transporting fecal or other similar chemical or biological matter. In this embodiment, the device has a generally cylindrical vessel **100** similar to the previous embodiments, however, in this embodiment, the end portion plug **101** is adapted to be readily secured and removed in an automated fashion by having a machine graspable radial outer surface having a plurality of facets **102** similar to the radial outer surface of a standard nut fastener. The plug is further formed to have an outer male threaded portion **103** on a first end and a breakable nib **108** on an opposite end which opens an access port **109**. The threaded portion **103** of the plug releasably engages an inner female threaded portion **104** in the end portion **105** of the vessel **100**. In this way, automated machinery can remove and replace the plug. To further encourage automated engagement of the facets, the surface of each facet may be angled inwardly toward the nib end of the plug. A resilient circumferential O-ring **107** provides for greater sealing against fluid leaks.

While the preferred embodiments of the invention have been described, modifications can be made and other embodiments may be devised without departing from the spirit of the invention and the scope of the appended claims.

WHAT IS CLAIMED IS: